K011284

JUN 2 0 2001

510(k) Summary

The as stated in the previous pages, this 510(k) submission to the Department of Health & Human Services, division of the FDA, for "Thin Film Dressing For Ultrasound Exam" has proposed a different intended use for adhesive films which are presently in commercial distribution.

The following information has been presented to aid in the evaluation of this 510(k) submission:

- The present CDRH product Classification for the film dressings is Class 1 and are 510(k) exempt.
- The indications stated in this 510(k) submission for using thin film dressing during an ultrasound exam, are the same indications which are stated in the packaging of the presently marketed and distributed adhesive films. (i.e. to cover: clean, surgical incisions; skin graft donor sites; pressures ulcers; superficial wounds / abrasions; chafed skin, etc.) The difference being is the intended use of such films to cover area of human anatomy during and ultrasound exam.
- Within this submission are a number of examples of these films including the present packaging, backing, and actual samples of films applied to paper.
- There are 20 examples of ultrasound imaging obtained both with adhesive film and without adhesive film applied to the surface that is being examined.
- The ultrasound images presented include that of a soft tissue phantom, superficial structures which include a standoff pad, superficial structures without a standoff pad, and deep structures.
- When considering predicate devices, there are devices presently marketed and distributed that serve a barrier during and ultrasound exam. These transducer covers are both sterile and non-sterile transducer covers which are made of the same material that are found in thin film dressings.

510(k) Truthful and Accurate Statement

This 510(k) Premarket Notification Submission of "Thin Film Dressing For Ultrasound Exam" has been produce and assembled by Dr. Martin E. Wendelken. All testing of the film and the images obtained & presented using an ultrasound scanner are indeed the actual pictures as stated. That the information contained within this submission represents actual results obtained using adhesive film dressings during an ultrasound exam, and such results are as presented. This submission to the FDA for evaluation is true and accurate as presented.

Dr. Martin E. Wendelken

05/3/2001
DATE

ANGELINA FLORES
NOTARY PUBLIC STATE OF N.Y.
03 8250600
QUALIFIED IN BRONX COUNTY
COMMISSION EXPIRES 1-31-03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2001

Dr. Martin E. Wendelken
610 Boulevard
ELMWOOD PARK NJ 07407

Re: K011284
Thin Film Dressing for Ultrasound Exam
Dated: April 27, 2001
Received: April 27, 2001
Regulatory Class: II
21 CFR 892.1570/Procode: 90 ITX
21 CFR 878.4020/Procode: 79 NAD

Dear Dr. Wendelken:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K011284

Device Name: THIN FILM DRESSING FOR ULTRASOUND EXAM

Indications For Use:

Ultrasound Film Dressing can be used as a **temporary** cover to protect an area of anatomy during and ultrasound exam. It may be used for both intact and non-intact skin. Common applications include to protect:

- Normal skin during a normal ultrasound exam
- Clean, closed surgical incisions during an ultrasound exam
- Skin graft donor sites during an ultrasound exam
- Superficial wounds such as abrasion, skin tears, and blisters during an ultrasound exam
- Chafed skin or irritated skin due to continuous exposure to moisture
- Pressure ulcers during an ultrasound exam

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011284